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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : ZHI et al.  
Serial No. : 10/589,920  
Filed : August 17, 2006  
Art Unit : 1614  
Examiner : Unknown  
Conf. No. : 3750  
Cust. No. : 20985  
Title : GLUCOCORTICOID RECEPTOR MODULATOR COMPOUNDS AND METHODS

**Mail Stop Amendment**  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

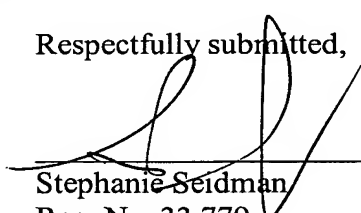
**TRANSMITTAL LETTER**

Dear Sir:

Transmitted herewith are an Information Disclosure Statement (3 pages), Forms PTO-1449 (3 pages), cited non U.S. patent references and a return postcard for filing in connection with the above-identified application. Because this Information Disclosure Statement is filed prior to receipt of a first office action on the merits in the above-referenced application, no fee is due. However, should it be determined that a fee for filing these papers is required, the Commissioner is authorized to charge Deposit Account No. 06-1050, as stated below:

☒ The Commissioner is hereby authorized to charge any fees that may be due in connection with this paper or with this application during its entire pendency to Deposit Account No. 06-1050. A duplicate of this sheet is enclosed.

Respectfully submitted,

  
Stephanie Seidman  
Reg. No. 33,779

Dated: November 21, 2006

Attorney Docket No. 18202-027US1 / 1110US  
**Address all correspondence to:**  
Stephanie Seidman  
Fish & Richardson P.C.  
12390 El Camino Real  
San Diego, California 92130  
Telephone: (858) 678-4777  
Facsimile: (202) 626-7796  
email: seidman@fr.com



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|------------|---|-----------|-----------|
| Applicant  | : ZHI et al.  | Art Unit  | : 1614    |
| Serial No. | : 10/589,920  | Examiner  | : Unknown |
| Filed      | : August 17, 2006   | Conf. No. | : 3750    |
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**INFORMATION DISCLOSURE STATEMENT IN ACCORDANCE  
WITH 37 C.F.R. §§ 1.97-1.98**

Because this Information Disclosure Statement is filed before the receipt of a First Office Action on the Merits for the above-captioned application, a fee for filing this statement should not be due. If, however, it is determined that a fee is due, any fees that may be due in connection with filing this paper may be charged to Deposit Account No. 06-1050.

In accordance with the duty of disclosure imposed by 37 C.F.R. §1.56 to inform the Patent Office of all information known by Applicant or Applicant's representative that may be material to the examination of the subject application, Applicant's representative hereby provides this Information Disclosure Statement that is prepared in accordance with 37 C.F.R. §1.97-1.98. Forms PTO-1449 (3 pages) and copies of the cited non U.S. Patent documents are provided herewith.

The documents cited on the Forms PTO-1449 are in the English language. Hence, in accordance with the requirements of 37 C.F.R. §1.98, as amended effective March 16, 1992, no further explanation of the listed items is necessary.

Applicant also makes known to the Examiner the following pending U.S., International and National Phase Applications that have one or more common inventors and/or are commonly owned:

Applicant : ZHI et al.  
Serial No. : 10/589,920  
Filed : August 17, 2006

Attorney's Docket No.: 18202-027US1 /1110US  
Information Disclosure Statement

| <u>Docket No.</u> | <u>U.S.S.N.</u> | <u>Filed</u> | <u>Publ. No.</u> |
|-------------------|-----------------|--------------|------------------|
| 002007/1002F      | 08/141,246      | 10/22/93     | n/a              |
| 002009/1002H      | 08/141,496      | 10/22/93     | n/a              |
| 002017/1002P      | 11/300,039      | 12/13/05     | 2006-0106072     |
| 004003/1026C      | 10/847,732      | 05/17/04     | 2004-0209839     |
| 005003/1028C      | 10/360,580      | 02/05/03     | 2004-0019072     |
| 013002/1062B      | 10/238,363      | 09/09/02     | 2003-0186970     |
| 013003/1062C      | 11/340,282      | 01/25/06     | n/a              |
| 015003/1073C      | 11/165,769      | 06/23/05     | 2005-0288350     |
| 017002/1081B      | 11/344,690      | 01/31/06     | 2006-0128740     |
| 018001/1082       | 10/080,503      | 02/22/02     | 2002-0183314     |
| 020002/1088B      | 11/411,676      | 04/25/06     | 2006-0194827     |
| 022US1/1096US     | 10/564,578      | 01/13/06     | n/a              |
| 028US1/1112US     | 10/590,119      | 08/18/06     | n/a              |
| 030US1/1111US     | 10/566,569      | 01/31/06     | n/a              |
| 033US2/1051BUS    | 11/448,365      | 06/06/06     | n/a              |
| 035002/1059B      | 10/229,649      | 08/27/02     | 2003-0013766     |
| 048001/1087       | 10/684,212      | 10/11/03     | 2004-0152717     |
| 057002/1091B      | 11/445,844      | 06/02/06     | 2006-0223839     |
| 072P01/P1123      | 60/753,302      | 12/21/05     | n/a              |

| <u>Docket No.</u> | <u>Intl. No.</u> | <u>Filed</u> | <u>Publ. No.</u> |
|-------------------|------------------|--------------|------------------|
| 023WO1/1097PC     | PCT/US04/023788  | 07/16/04     | 2005/009104      |
| 024WO1/1098PC     | PCT/US04/023093  | 07/16/04     | 2005/016255      |
| 026WO1/1100PC     | PCT/US04/023010  | 07/16/04     | 2005/010202      |
| 028WO1/1112PC     | PCT/US05/07867   | 03/11/05     | 2005/090282      |
| 068WO1/1119PC     | PCT/US06/23111   | 6/12/06      | Awaiting         |
| 069WO1/1124PC     | PCT/US06/26067   | 06/30/06     | Awaiting         |

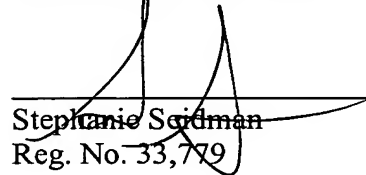
Although these documents are made known to the Patent and Trademark Office in compliance with Applicant's duty of disclosure, such disclosure is not to be construed as an admission by Applicant or Applicant's representative that any of the references, singly or in any combination thereof, is effective as prior art against the subject application. In accordance with 37 C.F.R. §1.97(g) and (h), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made or that no other material information as defined in 37 C.F.R. §1.56(b) exists.

Applicant : ZHI et al.  
Serial No. : 10/589,920  
Filed : August 17, 2006

Attorney's Docket No.: 18202-027US1 /1110US  
**Information Disclosure Statement**

Applicant respectfully requests that the Examiner review the foregoing references and they be made of record in the file history of the above-captioned application.

Respectfully submitted,



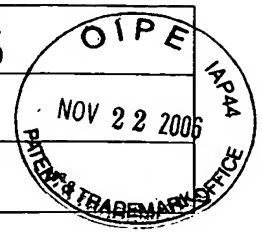
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Stephanie Seidman  
Reg. No. 33,779

Dated: November 21, 2006

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**Address all correspondence to:**  
Stephanie Seidman  
Fish & Richardson P.C.  
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Telephone: (858) 678-4777  
Facsimile: (202) 626-7796  
email: seidman@fr.com

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|--|--|--|--|-------------------------------|
| Substitute Form PTO-1449<br>(Modified)<br><br><b>Information Disclosure Statement<br/>by Applicant</b><br>(Use several sheets if necessary)<br><br>(37 CFR §1.98(b)) | U.S. Department of Commerce<br>Patent and Trademark Office |  | Attorney's Docket No.<br>18202-027US1/1110US | Application No.<br>10/589,920 |
|  | Applicant<br>ZHI et al.                                    |  |  |                               |
|  | Filing Date<br>August 17, 2006                             |  | Group Art Unit<br>1614                       |                               |



| U.S. Patent Documents |           |                 |                  |                 |       |          |                            |
|-----------------------|-----------|-----------------|------------------|-----------------|-------|----------|----------------------------|
| Examiner Initial      | Desig. ID | Document Number | Publication Date | Patentee        | Class | Subclass | Filing Date If Appropriate |
|                       | AA        | 2003/0073703    | 04/17/03         | Coghlan et al.  | 514   | 257      | 07/23/02                   |
|                       | AB        | Re 28,819       | 05/18/76         | Thompson        | 514   | 174      | 04/16/75                   |
|                       | AC        | 3,710,795       | 01/16/73         | Higuchi et al.  | 424   | 424      | 09/29/70                   |
|                       | AD        | 4,044,126       | 08/23/77         | Cook et al.     | 514   | 180      | 07/09/76                   |
|                       | AE        | 4,328,245       | 05/04/82         | Yu et al.       | 514   | 530      | 02/13/81                   |
|                       | AF        | 4,358,603       | 11/09/82         | Yu              | 560   | 2        | 04/16/81                   |
|                       | AG        | 4,364,923       | 12/21/82         | Cook et al.     | 424   | 46       | 04/30/81                   |
|                       | AH        | 4,409,239       | 10/11/83         | Yu              | 514   | 530      | 01/21/82                   |
|                       | AI        | 4,410,545       | 10/18/83         | Yu et al.       | 514   | 530      | 05/10/82                   |
|                       | AJ        | 4,414,209       | 11/08/83         | Cook et al.     | 514   | 180      | 06/13/77                   |
|                       | AK        | 4,522,811       | 06/11/85         | Eppstein et al. | 514   | 2        | 07/08/82                   |
|                       | AL        | 4,981,784       | 01/01/91         | Evans et al.    | 435   | 6        | 11/30/88                   |
|                       | AM        | 5,033,252       | 07/23/91         | Carter          | 53    | 425      | 07/30/90                   |
|                       | AN        | 5,052,558       | 10/01/91         | Carter          | 206   | 439      | 07/27/90                   |
|                       | AO        | 5,071,773       | 12/10/91         | Evans et al.    | 436   | 501      | 10/20/87                   |
|                       | AP        | 5,323,907       | 06/28/94         | Kalvelage       | 206   | 531      | 03/15/93                   |
|                       | AQ        | 5,506,102       | 04/09/96         | McDonnell       | 435   | 6        | 10/28/93                   |
|                       | AR        | 5,688,810       | 11/18/97         | Jones et al.    | 514   | 311      | 06/05/95                   |
|                       | AS        | 5,693,646       | 12/02/97         | Jones et al.    | 514   | 285      | 06/05/95                   |
|                       | AT        | 5,696,127       | 12/09/97         | Jones et al.    | 514   | 285      | 06/05/95                   |
|                       | AU        | 5,696,133       | 12/09/97         | Jones et al.    | 514   | 314      | 06/05/95                   |
|                       | AV        | 6,068,976       | 05/30/00         | Briggs et al.   | 435   | 6        | 03/19/96                   |
|                       | AW        | 6,380,207       | 04/30/02         | Coghlan et al.  | 514   | 285      | 02/13/98                   |
|                       | AX        | 6,506,766       | 01/14/03         | Coghlan et al.  | 514   | 285      | 07/05/02                   |
|                       | AY        | 6,696,459       | 02/24/04         | Jones et al.    | 514   | 285      | 10/14/97                   |

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| Examiner Signature   | Date Considered |
| EXAMINER: Initials citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. |                 |

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|--|--|--|-------------------------------|
| Substitute Form PTO-1449<br>(Modified)   | U.S. Department of Commerce<br>Patent and Trademark Office | Attorney's Docket No.<br>18202-027US1/1110US | Application No.<br>10/589,920 |
| <b>Information Disclosure Statement<br/>by Applicant</b><br>(Use several sheets if necessary)<br>(37 CFR §1.98(b)) |  | Applicant<br>ZHI et al.                      |                               |
|  |  | Filing Date<br>August 17, 2006               | Group Art Unit<br>1614        |

| Foreign Patent Documents or Published Foreign Patent Applications |           |                 |                  |                          |       |          |             |    |
|---|-----------|-----------------|------------------|--------------------------|-------|----------|-------------|----|
| Examiner Initial  | Desig. ID | Document Number | Publication Date | Country or Patent Office | Class | Subclass | Translation |    |
|   |           |                 |                  |                          |       |          | Yes         | No |
|   | AZ        | 03/037905       | 05/08/03         | PCT                      |       |          |             |    |
|   | BA        | 02/02565        | 01/10/02         | PCT                      |       |          |             |    |
|   | BB        | 99/041257       | 08/19/99         | PCT                      |       |          |             |    |
|   | BC        | 99/041256       | 08/19/99         | PCT                      |       |          |             |    |
|   | BD        | 95/031722       | 11/23/95         | PCT                      |       |          |             |    |
|   | BE        | 96/029405       | 09/26/96         | PCT                      |       |          |             |    |
|   | BF        | 96/019458       | 06/27/96         | PCT                      |       |          |             |    |
|   | BG        | 1053239         | 01/08/03         | EP                       |       |          |             |    |
|   | BH        | 1053240         | 04/16/03         | EP                       |       |          |             |    |
|   | BI        | 1382597         | 01/21/04         | EP                       |       |          |             |    |

| Other Documents (include Author, Title, Date, and Place of Publication) |           |  |
|---|-----------|--|
| Examiner Initial  | Desig. ID | Document   |
|   | BJ        | Allegretto et al., "Transactivation properties of retinoic acid and retinoid X receptors in mammalian cells and yeast. Correlation with hormone binding and effects of metabolism," <i>Journal of Biological Chemistry</i> , 268(35):26625-26633, (1993). Erratum in: <i>Journal of Biological Chemistry</i> , 269(10):7834, (1994). |
|   | BK        | Ansel, H.C., <i>Introduction to Pharmaceutical Dosage Forms</i> , Fourth Edition, Lea and Febiger, Philadelphia, P.A., p. 126, (1985).   |
|   | BL        | Bains and Tacke, "Silicon chemistry as a novel source of chemical diversity in drug design," <i>Current Opinion in Drug Discovery and Development</i> , 6(4):526-543, (2003).  |
|   | BM        | Berger et al., "Interaction of glucocorticoid analogues with the human glucocorticoid receptor," <i>Journal of Steroid Biochemistry and Molecular Biology</i> , 41:733-748, (1992).  |
|   | BN        | Cheng and Prusoff, "Relationship between the inhibition constant (K <sub>i</sub> ) and the concentration of inhibitor which causes 50 per cent inhibition (I <sub>50</sub> ) of an enzymatic reaction," <i>Biochemical Pharmacology</i> , 22:3099-3108, (1973).  |
|   | BO        | Edwards et al., "Preparation, resolution, and biological evaluation of 5-aryl-1,2-dihydro-5H-chromeno[3,4-f]quinolines potent, orally active, nonsteroidal progesterone receptor agonists," <i>Journal of Medicinal Chemistry</i> , 41(15):2779-2785, (1998).  |
|   | BP        | Evans et al., "The steroid and thyroid hormone receptor superfamily," <i>Science</i> , 240:889-895, (1988).  |
|   | BQ        | Fingl et al., <i>The Pharmacological Basis of Therapeutics</i> , Ch. 1, Eds. Goodman and Gilman, Macmillan Publishing Co., New York, N.Y., pp. 1-46, (1975).   |
|   | BR        | Nogady, T., <i>Medicinal Chemistry A Biochemical Approach</i> , Oxford University Press, New York, N.Y., pp. 388-392, (1985).  |

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| <b>Information Disclosure Statement<br/>by Applicant</b><br>(Use several sheets if necessary)<br>(37 CFR §1.98(b)) |  | Applicant<br>ZHI et al.                      |                               |
|  |  | Filing Date<br>August 17, 2006               | Group Art Unit<br>1614        |

| Other Documents (include Author, Title, Date, and Place of Publication) |           |   |
|---|-----------|---|
| Examiner Initial  | Desig. ID | Document  |
|   | BS        | O'Reilly et al., "Cotransfection and recombinant virus identification" in <i>Baculovirus Expression Vectors</i> , Ch. 13, O'Reilly et al., Eds., W. H. Freeman, New York, N.Y., pp. 139-179, (1992).                                  |
|   | BT        | Pathirana et al., "Nonsteroidal human progesterone receptor modulators from the marine alga <i>Cymopolia barbatam</i> ," <i>Molecular Pharmacology</i> , 47:630-635, (1995).  |
|   | BU        | Pooley et al., "Discovery and preliminary SAR studies of a novel, nonsteroidal progesterone receptor antagonist pharmacophore," <i>Journal of Medicinal Chemistry</i> , 41:3461-3466, (1998).   |
|   | BV        | Srinivasan and Thompson, "Overexpression of full-length human glucocorticoid receptor in <i>Spodoptera frugiperda</i> cells using the baculovirus expression vector system," <i>Molecular Endocrinology</i> , 4(2):209-216, (1990).   |
|   | BW        | Tacke and Zilch, "Sila-substitution--a useful strategy for drug design?" <i>Endeavour</i> , 10:191-197, (1986).   |
|   | BX        | Tegley et al., "5-Benzylidene 1,2-dihydrochromeno[3,4-f]quinolines, a novel class of nonsteroidal human progesterone receptor agonists," <i>Journal of Medicinal Chemistry</i> , 41(22):4354-4359, (1998).                            |
|   | BY        | Zhi et al., "5-Alkyl 1,2-dihydrochromeno[3,4-f]quinolines a novel class of nonsteroidal progesterone receptor modulators," <i>Bioorganic and Medicinal Chemistry Letters</i> , 8(23):3365-3370, (1998).                               |
|   | BZ        | Zhi et al., "5-Aryl-1,2,3,4-tetrahydrochromeno[3,4-f]quinolin-3-ones as a novel class of nonsteroidal progesterone receptor agonists effect of A-ring modification," <i>Journal of Medicinal Chemistry</i> , 42(8):1466-1472, (1999). |
|   | CA        | Zhi et al., "5-Aryl-1,2-dihydrochromeno[3,4-f]quinolines a novel class of nonsteroidal human progesterone receptor agonists," <i>Journal of Medicinal Chemistry</i> , 41(3):291-302, (1998).  |
|   | CB        | Zhi et al., "5-benzylidene-1,2-dihydrochromeno[3,4-f]quinolines as selective progesterone receptor modulators," <i>Journal of Medicinal Chemistry</i> , 46(19):4104-4112, (2003).   |
|   | CC        | Zhi et al., "Development of progesterone receptor antagonists from 1,2-dihydrochromeno[3,4-f]quinoline agonist pharmacophore," <i>Bioorganic and Medicinal Chemistry Letters</i> , 13(12):2075-2078, (2003).                          |
|   | CD        | Zhi et al., "Synthesis and biological activity of 5-methylidene1,2-dihydrochromeno[3,4-f]quinoline derivatives as progesterone receptor modulators," <i>Bioorganic and Medicinal Chemistry Letters</i> , 13(12):2071-2074, (2003).    |
|   | CE        | Zhi et al., "Nonsteroidal progesterone receptor antagonists based on 6-thiophenehydroquinolines," <i>Bioorganic and Medicinal Chemistry Letters</i> , 10:415-418, (2000).   |

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